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Andrew Butterworth

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,931	Applicant(s) BUTTERWORTH, ANDREW	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-52 is/are pending in the application.
- 4a) Of the above claim(s) 32-35, 42, 43, 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-31, 36-41 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, drawn to the vaginal thermometer for sensing temperature of claims 23-31, 36-41, and 44-50, and Species B, embodiment drawn to the electronic embodiment of the apparatus of Figure 2, in the reply filed on 12/22/2008 is acknowledged. The traversal is on the ground(s) that an undue burden does not exist and the search would be coextensive. This is not found persuasive because under PCT Rules 13.2 and 13.1 the inventions lack the same or corresponding special technical feature and the species are not so linked to form a single general inventive concept, respectively.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 32-35, 42, 43, 51, and 52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/22/2008.

Claim Objections

3. Claim 27 is objected to because of the following informalities: the positive recitation of "thehousing" in line 1 should apparently read "the housing". Appropriate correction is required.

4. Claims 27, 40, and 49 are objected to because of the following informalities: the capitalization of some of the materials in the Markush group appears informal.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. There are two occurrences of claim 36, an independent one and a dependent one. Claims 37-41 depend on claim 36. The claims are indefinite because the scope of the claims is indeterminate with respect to the apparent inadvertent mis-numbering and the dependencies set forth therein.

8. The Examiner notes for the purposes of examination on the merits. The first positive recitation of claim 36 is being treated as independent, the second positive recitation of claim 36 (hereinafter 36a) is being treated as depending therefrom, and claims 37-41 are being treated as being either directly and/or indirectly on the first positive recitation of claim 36 (i.e. claim 40 still depends on claim 39 which depends on the first positive recitation of claim 36).

9. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the essential elements corresponding to the relationship between the thermometer, the temperature data, and the determination of ovulation in the subject mammal. As broadly as claimed the scope of the claim is indeterminate with respect to how “the thermometer is configured to be used to determine ovulation in the subject mammal”.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 23-31, 36-41, and 44-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Guice et al. (US 2002/0010390 A1, hereinafter Guice).

12. For claim 23, Guice discloses and shows a vaginal indwelling thermometer for use in the vagina of a subject mammal (paragraphs 121-137, 154-156, 160-163, and 178-179) (as best seen in Figures 12, 13, and 17-22), the thermometer comprising *inter alia*:

- a housing (290 and 296) (as best seen in Figure 12) (paragraphs 121-137, 154-156, 160-163, and 178-179) enclosing:
- a temperature sensing means (292) (as best seen in Figure 12) (paragraphs 135-137) which generate data indicative of the *per vaginam* temperature of the subject mammal (as best seen in Figure 12) (paragraphs 121-137, 154-156, 160-163, and 178-179); and
- a temperature recording means (286) (as best seen in Figure 12) (paragraphs 135-137) integral with the temperature sensing means (as best seen in Figure 12) (paragraphs 121-137, 154-156, 160-163, and 178-179);
- wherein the temperature recording means records temperature data generated by the temperature sensing means (paragraphs 135-137),
- wherein the vaginal indwelling thermometer is configured to be left in a vagina of a subject mammal for a long period of time without causing discomfort to said subject and without being easily lost (paragraphs 155, 160-163, and 178-179).

13. For claim 36, Guice discloses and shows a device for the prediction of ovulation in a subject mammal (paragraphs 121-137, 154-156, 160-163, and 178-179) (as best seen in Figures 12, 13, and 17-22), the device comprising *inter alia*:

- a housing (290 and 296) (as best seen in Figure 12) (paragraphs 121-137, 154-156, 160-163, and 178-179) configured to be left in a vagina of said subject mammal for a long period of time without causing discomfort to said subject and without being easily lost (paragraphs 155, 160-163, and 178-179);

- a temperature sensing means (292) (paragraphs 135-137) located within said housing (as best seen in Figure 12) for generating data indicative of the *per vaginam* temperature of the subject mammal (paragraphs 121-137, 154-156, 160-163, and 178-179);
- a temperature recording means (286) (as best seen in Figure 12) (paragraphs 135-137) located within the housing (as best seen in Figure 12) which records the temperature data generated by the temperature sensing means (paragraphs 135-137);
- a removal means (paragraph 179) associated with said housing (paragraph 179); and
- a means for connecting (282) said device, once removed from said vagina of said subject mammal, to means for reading and interpreting said recorded data (paragraph 135) wherein said device is configured to be worn *per vaginam* for at least one complete menstrual cycle (paragraphs 122-123, 136-137, 156, and 179).

14. For claim 44, Guice discloses and shows a device for the detection of infection in a subject mammal (paragraphs 121-137, 154-156, 160-163, and 178-179) (as best seen in Figures 12, 13, and 17-22), the device comprising *inter alia*:

- a housing (290 and 296) (as best seen in Figure 12) (paragraphs 121-137, 154-156, 160-163, and 178-179) configured to be left in an ear or a vagina of said subject mammal for a long period of time without causing discomfort to said subject and without being easily lost (paragraphs 155, 160-163, and 178-179);

- a temperature sensing means (292) (paragraphs 135-137) located within said housing (as best seen in Figure 12) for generating data indicative of the core body temperature of the subject mammal (paragraphs 121-137, 154-156, 160-163, and 178-179);
- a temperature recording means (286) (as best seen in Figure 12) (paragraphs 135-137) located within the housing (as best seen in Figure 12) which record the temperature data generated by the temperature sensing means (paragraphs 135-137);
- a removal means (paragraph 179) associated with said housing (paragraph 179); and
- a means for connecting (282) said device, once removed from said ear or vagina of said subject mammal, to means for reading and interpreting said recorded data (paragraph 135).

15. For claims 24, 36a, and 45, Guice discloses and shows the vaginal thermometer, wherein the temperature sensing means is an electronic temperature sensing means (paragraph 179).

16. For claims 25, 37, and 46, Guice discloses and shows the vaginal thermometer, wherein the temperature sensing means comprises a thermistor (paragraph 179).

17. For claims 26, 39, and 48, Guice discloses and shows the vaginal thermometer, the housing comprises a biocompatible material (paragraphs 155-163).

18. For claims 27, 40, and 49, Guice discloses and shows the vaginal thermometer, wherein the housing is formed from a material comprising thermoplastic urethane (paragraph 163).

19. For claims 28, 41, and 50, Guice discloses and shows the vaginal thermometer, the temperature sensing means is capable of recording data every 20 minutes (paragraphs 100-104 and 106).

20. For claims 29, 38, and 47, Guice discloses and shows the vaginal thermometer, wherein said subject mammal is capable of being human (as best seen in Figures 12, 13, and 17-22).

21. For claim 30, Guice discloses and shows the vaginal thermometer, wherein the thermometer is configured to be worn *per vaginam* for at least one entire menstrual cycle (paragraphs 122-123, 136-137, 156, and 179).

22. For claim 31, Guice discloses and shows the vaginal thermometer, wherein the thermometer is capable of determining ovulation in the subject mammal (paragraphs 122-123, 136-137, 156, and 179).

Response to Arguments

23. Applicant's arguments with respect to claims 23-31, 36-41, and 44-50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

24. The prior art made of record, cited on the accompanying PTO-892, and not relied upon is considered pertinent to applicant's disclosure. The prior art discloses, shows, and teaches vaginal temperature measurement thermometers.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736